

Q8 10. (amended) The sample vial of claim [9] 1 wherein said torque pattern comprises six [generally] radially disposed equi-spaced ribs.

Q9 12. (amended) The sample vial of claim [11] 1 wherein said body comprises a plurality of circumferentially-disposed lugs.

QH 15. (amended) The sample vial of claim 1 wherein said body further comprises fluid level indicia disposed on said [generally cylindrical] outer surface thereof.

REMARKS

The Office Action has been carefully considered and the foregoing amendment made in response thereto. Claims 1-25 are pending in the application. Claims 1-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite; claims 1, 9, and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Warder et al. (U.S. Pat. No. 4,872,563); claims 1-2, 4, 9-12, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wiedmann (U.S. Des. Pat. No. 244,555); claims 3, 5-8, 13, 15-18, and 21-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Jensen et al. (U.S. Pat. No. 4,917,867); and claims 19-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Cytac Corporation, ThinPrep 2000 Operator's Manual (1995).

In view of the above amendment and following remarks, reconsideration and withdrawal of the rejection of claims 1-25 are respectfully requested.

1. Claims 1-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the term "generally" in claims 1, 9-10, and 15 is deemed to render the claims indefinite.

Applicants respectfully submit that the claims are sufficiently definite, given the nature of the claimed structure and the level of skill in the art. As stated in the MPEP at section 2173.02, the Examiner:

...should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted, even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

(emphasis in original)

Applicants respectfully submit that the use of the term "generally" to describe the contour of the outer surface of the sample vial body and the orientation of the rib(s) on the vial cap, taken in conjunction with the disclosure in the specification and drawings, are sufficient to reasonably apprise one of ordinary skill in the art of the scope of the invention.

Nonetheless, in order to advance prosecution, Applicants are amending claims 1, 10, and 15 to cancel the objectionable term. Claim 9 has been cancelled. Reconsideration and withdrawal of the rejection of claims 1-25 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

2. Claims 1, 9, and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Warder et al. ("Warder"). Applicants respectfully traverse this rejection to the extent applicable to the claims as amended.

Briefly, Warder discloses a disposable protective enclosure or shipping device 10 for transporting hazardous materials contained in a stoppered vial 52. The device 10 includes a cylindrical enclosure 12 with a mating top 14 having a rounded dome section 42 and a pair of indentations 44 which present gripping surfaces for fingers of a user. When the top 14 is inserted into the enclosure 12, mating detent 24 and channel 38 lock the top 14 in place. To remove the top 14, a tab 30 on the enclosure 12 must be pulled, breaking open the side of the enclosure 12 along lines of weakness 28. The vial 52 can then be removed and the shipping device 10 thereafter discarded.

Applicants' invention is drawn to a sample vial having structure adapted for use in an automated test apparatus. The sample vial includes a cylindrical body having at least one anti-rotation lug about an outer surface of the body. A mating, releasably engagable threaded cap includes a torque pattern on an outer surface thereof. The torque pattern may include one or more radially disposed ribs configured to mate with a rotatable interface of the automated test apparatus. A seal is provided between the body and the cap, the seal being capable of forming a substantially fluid-tight seal therebetween to prevent leakage of fluid therein.

In order to anticipate a claim under 35 U.S.C. § 102(b), a single prior art reference must disclose each and every limitation of the claim. Applicants respectfully submit that Warder fails to meet this exacting standard with respect to the claims, as amended.

Independent claim 1 has been amended to define the torque pattern on the cap as being "a plurality of radially disposed ribs," which are used as reaction surfaces by the automated test apparatus rotatable interface, in combination with the "anti-torque lug," to unscrew or screw the cap on the body. No new matter has been entered thereby, antecedent basis for the amendment being found, for example, in dependent claims 9 and 11 (now both cancelled), the specification at page 9, lines 8-17, and FIGS 1 and 3.

Warder, on the other hand, discloses a top 14 having a rounded dome section 42 and a pair of indentations 44 which present gripping surfaces for fingers of a user. The design of Warder provides for pulling the top 14 axially from the cylindrical enclosure 12 once the tab 30 is pulled and the enclosure 12 is split open. There are no "plurality of radially disposed ribs" in the top 14 of Warder nor is there any motivation to apply a relative torque to the top 14-and-body 12, because there are no screw threads, bayonet-style retention feature, or the like. The top 14 in Warder is installed and removed axially.

Further, Applicants claim in independent claim 1 the body having "an outer surface...and at least one anti-torque lug about said body outer surface..." As stated in Applicants' specification at page 8, lines 21-26:

In one embodiment, depicted in FIG. 1, the vial body 12 includes six circumferentially disposed anti-rotation lugs 18, equi-spaced on an outer surface of the body 12. The anti-rotation lugs 18 are adapted for use with a storage tray and/or vial sleeve, as will be discussed in greater detail hereinbelow with respect to FIGS. 7A and 7B. The lugs 18 prevent rotation of the body 12, thereby facilitating automated removal and reinstallation of the cap 14.

The Office Action states that Warder teaches Applicants' claimed lug as element 26 in FIG. 1. Applicants respectfully disagree. Element 26 of Warder, described as a "lip," is represented as a radially extending circumferentially uniform flange. Accordingly, lip 26 would not provide an anti-rotation function, as Applicants' claimed lug does. While the enclosure 12 of Warder does include a tab 30 for splitting open the enclosure 12, Warder states, at col. 2, lines 35-43:

As noted in FIG. 1, enclosure 12 is provided with two vertically extending lines of weakness 28, each of which is designed in the drawing by closely spaced parallel broken lines. Integrally formed into top body section 18 in the area between lines of weakness 28 is a tab 30 which is positioned beneath lip 26. By virtue of extending outwardly at least as far as tab 30, lip 26 offers protection against accidental opening of the tab during shipment.

Accordingly, the tab 30 of Warder is structurally and functionally distinct from Applicants' claimed anti-rotation lug. An attempt to use the tab 30 of Warden as an anti-rotation lug would cause the enclosure 12 to be breached. Further, there is no motivation to use tab 30 as an anti-rotation feature, because the top 14 is removed axially from the enclosure 12 rather than torsionally, as is required with a screw thread, bayonet-style retention feature, or the like.

Moreover, in independent claim 1, Applicants claim "*a seal disposed between said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween.*" Applicants respectfully submit that the element cited in the Office Action, namely channel 38, is not a seal. The mating channel 38 (formed in the top 14) and detent 24 (formed in the enclosure 12) act to lock the top 14 in place. To remove the top 14, the tab 30 on the enclosure 12 must be pulled, breaking open the side of the enclosure 12 along lines of weakness 28.

Sealing in Warder is performed by liners 32, 48. At col. 2, lines 44-46, and lines 62-64, Warder states:

} not
 knock
 in
claim

The inside of body section 16 is lined with a water impervious liner 32 made of polyethylene or other suitable material...

With reference to FIG. 2, the inside of top 14 is lined with a water impervious liner 48 constructed of the same material as liner 32.

Accordingly, there is no disclosure in Warder of an independent "seal disposed *between* said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween," as disclosed and claimed by Applicants.

For all these reasons, Applicants respectfully submit that amended independent claim 1 is not anticipated by Warder. Because claim 25 depends from independent claim 1 and contains all the limitations thereof, Applicants respectfully submit that claim 25 is patentable as well. Claim 9 has been cancelled. Reconsideration and withdrawal of the rejection of claims 1 and 25 under 35 U.S.C. § 102(b) as being anticipated by Warder are respectfully requested.

3. Claims 1-2, 4, 9-12, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wiedmann. Applicants respectfully traverse this rejection as applicable to the claims, as amended.

The design patent of Weidmann appears to disclose a covered test tube. Due to the poor quality of the figures of Weidmann and the dearth of disclosure in the design patent, Applicants are unable to ascertain those features of Weidmann which the Examiner considers to disclose the claimed "at least one lug about said body outer surface" for anti-rotation, the "torque pattern on said cap outer surface...comprising a plurality of radially disposed ribs," and the "seal disposed between said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween."

For example, the four projections proximate the opening of the test tube depicted in perspective in FIG. 1 are nowhere to be seen in the side view of FIG. 2. Accordingly, this structure does not appear to anticipate Applicants claimed anti-rotation lug, but rather may be structure used to retain the test tube cover. Similarly, the six small nubs on the cover depicted in FIG. 3 do not appear to anticipate Applicants' claimed "torque pattern on said cap outer surface...")

comprising a plurality of radially disposed ribs.” The cover appears knurled, to facilitate manual installation and removal of the cover. There is no indication that the nubs are useful as a torque pattern for mating with an automated test apparatus rotatable interface for automatic installation and removal of the cover. As to the statement in the Office Action that Applicants’ claimed “fluid-tight seal” is inherent, Applicants respectfully submit that absent disclosure in the reference regarding the existence of a seal and the use to which the covered test tube is to be put (e.g., to seal fluids therein), Weidmann fails to be a proper anticipatory reference on this ground as well.

) not disclosed

For all these reasons, Applicants respectfully submit that amended independent claim 1 is not anticipated by Weidmann. Because claims 2, 4, 10, 12, and 14 depend from independent claim 1 and contains all the limitations thereof, Applicants respectfully submit that these claims are patentable as well. Claims 9 and 11 have been cancelled and claims 10 and 12 amended to depend from claim 1. Reconsideration and withdrawal of the rejection of claims 1-2, 4, 10, 12, and 14 under 35 U.S.C. § 102(b) as being anticipated by Weidmann are respectfully requested.

4. Claims 3, 5-8, 13, 15-18, and 21-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Jensen et al. (“Jensen”). Applicants respectfully traverse this rejection to the extent applicable to the claims as amended.

Briefly, Jensen discloses an apparatus 10 for collecting and transportation dual biological samples. The apparatus 10 includes a threaded outer container 12 and lid 14. Disposed in the container 12 are, *inter alia*, a threaded specimen vial 28 with lid 30.

Applicants respectfully submit that Jensen fails to cure the deficiencies of Wiedmann with respect to independent claim 1. For example, Jensen fails to disclose the claimed “at least one lug about said body outer surface” for anti-rotation. The container 12 and specimen vial 28 of Jensen appear to be plain, cylindrical elements. Jensen also fails to disclose the claimed “torque pattern on said cap outer surface...comprising a plurality of radially disposed ribs.” The container lid 14 is plain and the specimen vial lid 30 has a simple knurled edge for manual gripping. Accordingly, the combination of Jensen and Weidmann fails to render Applicants’

) Wiedmann is related to Jensen

claim 1, as amended, obvious. Accordingly, dependent claims 3, 5-8, 13, 15-18, and 21-25 are patentable as well.

Further, with respect to claims 3 and 5, there does not appear to be any disclosure in Weidmann and Jensen that the container, vial, and/or lids are made of polypropylene. Rather Jensen discloses at col. 4, lines 1-3, that the specimen vial body 28 is made of "a uniform mixture of polystyrene and K-resin..." With respect to claims 7 and 8, there is no disclosure of torque values for making a substantially fluid-tight seal. Rather, Jensen discloses at col. 4, lines 39-47, using a styrene foam sealing disk 60 having an adhesive coated surface 62 to seal the specimen vial 28. Regarding claim 16, there is no disclosure of the fluid level indicia being a frosted band. With respect to claim 24, there is no disclosure of sample indicia being a bar code. Lastly, with respect to claim 25, there is no disclosure of a flange proximate the open end of the vial body.

*obvious
bar code*

Accordingly, reconsideration and withdrawal of the rejection of claims 3, 5-8, 13, 15-18, and 21-25 under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Jensen are respectfully requested.

5. Lastly, claims 19-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Cytac Corporation, ThinPrep 2000 Operator's Manual (1995). Applicants respectfully traverse this rejection as applied to the claims as amended.

The operator's manual discloses capping a PreservCyt™ sample vial, stating: "Line on cap and line on vial should meet or slightly overlap."

Applicants respectfully submit that the operator's manual fails to cure the deficiencies of Wiedmann with respect to independent claim 1. For example, the operator's manual fails to disclose the claimed "at least one lug about said body outer surface" for anti-rotation. The sample vial in the manual appears to be plain, cylindrical element. The operator's manual also fails to disclose the claimed "torque pattern on said cap outer surface...comprising a plurality of radially disposed ribs." The sample vial lid is plain, with simple knurled edging for manual

gripping. Accordingly, the combination of the operator's manual and Weidmann fails to render Applicants' claim 1, as amended, obvious. Accordingly claims 19-20 are patentable as well.

Reconsideration and withdrawal of the rejection of claims 19-20 under 35 U.S.C. § 103(a) as being unpatentable over Wiedmann in view of Cytac Corporation, ThinPrep 2000 Operator's Manual (1995) are respectfully requested.

6. Applicants wish to bring to the Examiner's attention that U.S. Pat. No. 4,872,563 to Warder et al., which was applied by the Examiner to reject certain claims, does not appear to be of record in the instant application. The patent is nowhere cited on any Form PTO-892 or PTO-1449. Correction is respectfully requested.

Conclusion

In view of the foregoing, Applicants respectfully request entry of this amendment, reconsideration, and allowance of claims 1-8, 10, and 12-25 in due course. The Examiner is invited to telephone Applicants' undersigned representative to discuss any outstanding issues.

Respectfully submitted,

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